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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,018	12/16/2005	Livius Cotarca	281879US0PCT	5959
22850 7590 01/11/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
			EXAMINER NAGUBANDI, LALITHA	
			ART UNIT 1621	PAPER NUMBER
			NOTIFICATION DATE 01/11/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/561,018	Applicant(s) COTARCA ET AL.	
	Examiner Lalitha Nagubandi	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/16/2005;9/7/2006;12/15/2006 and9/6/2007.

Detailed Action

Status of the Claims

1. Claims 1-5 are pending. Claims 1- 5, are considered for examination in this office action.

Specification

2. The disclosure is objected to because of the following informalities: In line 3, the word 'anti-epilectic' should be replaced with the word "anti-epileptic". Appropriate correction is required. Applicant's cooperation is requested in correcting any further errors of which applicant may become aware in the specification.

Claim Objections

3. Claim 1 is objected to because of the following informalities: In claim 1, line 3 the word 'cristallization' should be replaced with "crystallization". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Augart et al (US Pat No. 6,054,482) in view of Itoh et al (US Pat No. 5,279,744).

Applicants' claim a process for the preparation of gabapentin, which comprises, the passage of a gabapentin inorganic salt through a strong cationic ionic exchange resin, and eluting gabapentin with ammonia and alkaline hydroxide aqueous solution. The process further embodies neutralization of the gabapentin sodium salt by HCl and crystallization of gabapentin from alcoholic solvents.

Determination of the scope and content of prior art

Augart et al teach, (please see col. 6, lines 34-53) a method for the preparation of pure gabapentin which comprises of contacting a solution containing the corresponding hydrochloride with an anion exchange resin (IRA 68) in basic form followed by concentration and recrystallisation from methanol.

Itoh et al teach, (col. 4, lines 35-59) an improved process for the purification of amino acids from fermentation broths, by contacting them with an strongly acidic cationic ion-exchange resin followed by elution with ammonia solution.

Ascertainment of difference between the prior art and the claims

The difference between the prior art and in the instant claims is that Augart et al teach anion exchange resin, whereas the instant claims employs cation exchange resin. However, Itoh teaches cationic exchange resins but suggests that any type of ion exchange resin may be used for the purpose.

Finding of prima facie obviousness-rationale and motivation

Thus one of ordinary skill in the art would have been motivated by the suggestion of Itoh to use a cationic resin in the process of Augart for the purification of cyclic amino acids. Moreover, it would have been obvious to use the cation exchange resin taught by Itoh in the process of Augart with a reasonable expectation of success in eluting gabapentin inorganic salt and subjecting it to further crystallization process.

The instantly claimed process would therefore have been obvious to one of ordinary skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Instant claims are directed to a process for the preparation of gabapentin which comprises the passage of a gabapentin inorganic salt through a strong cationic ionic exchange resin.

The claims in the copending application No. **10/582,790** are directed to a process for the preparation of Gabapentin comprising passage of a salt of gabapentin through a column comprising an ionic exchange resin of strong cationic type as embodied in claims **1,2,3,4, 7,8,9,10,11,12,15,16,19,21,22**.

Based on the above findings the following rejection has been made.

Claims **1-5** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **1,2,3,4, 7,8,9,10,11,12,15,16,19,21,22** of copending application No. **10/582,790**.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim **1** is generic to all that is recited in claims **1** and **9** of the co-pending application No. **10/582,790**. That is, the claims **1** and **9** of the copending application No. **10/582,790** fall entirely within the scope of claim **1**, or in

other words, claim 1 is obviated by the claims 1 and 9 of the copending application No. **10/582,790** . Specifically the process of preparing Gabapentin, comprising the passage of a gabapentin inorganic salt through a strong cationic ionic exchange resin and using an aqueous solution of ammonia and alkaline hydroxide.

Further, claims **2-5** are generic to all that is recited in **2,3,4, 7,8,9,10,11,12,15,16,19,21,22** claims of the copending application No. **10/582,790**. Thus the instant claims encompass the claims in the copending application No. **10/582,790** and are related as genus and species, and are coextensive in scope.

Therefore the instantly claimed process of preparing Gabapentin is obvious over the claims in the copending application. Thus the instant claims are rejected under provisional obviousness-type of double patenting.

The claims in the copending application No. **11/390,451** are directed to a process for the preparation of Gabapentin comprising passage of a salt of gabapentin through a column comprising an ionic exchange resin of *strong cationic resin* as embodied in claims **1,2,3 ,4, 7,8,9,10,11,12,15,16,19,21,22**.

Upon further examination, of the co-pending application No. **11/390,451** the following rejection has been made:

Claims **1-5** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **1-4, 16,17,18,22,23,25,27, and 28** of copending application No. **11/390,451**

Although the conflicting claims are not identical, they are not patentably distinct from each other because base claim 1 of the instant application is well within the scope of base claim 1 of the copending application where, the claim recite method of separating gabapentin with an ion exchange resin more specifically cationic resin. Although the conflicting claim is not identical, they are not patentably distinct from each other because the claim 1 is generic to all that is recited in claims 1 of copending application No. 11/390,451. Similarly, claims 2-5 of the instant application embrace the claims 2-4, 16,17,18,22,23,25,27, and 28 of the copending application.

Therefore the instantly claimed process of preparing Gabapentin is obvious over the claims in the copending application. Thus the instant claims are rejected under provisional obviousness-type of double patenting.

Conclusion

6. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalitha Nagubandi whose telephone number is 571 272 7996. The examiner can normally be reached on 6.30am to 3.30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne, Eyler can be reached on 571 272 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lalitha Nagubandi

Patent Examiner
Technology Center 1600

December 19th 2007

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PRIMARY EXAMINER


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12/19/2007